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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,811	09/08/2003	Mark Ledebot	VPI/02-121 US	1126
27916	7590	08/16/2006	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			OLSON, ERIC	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,811	LEDEBOER ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>March 19, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This application claims benefit of provisional application 60/408813, filed September 6, 2002. Claims 1-23 are pending in this application and examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims recite the limitation, "R² is substituted or unsubstituted cycloalkyl." This phrase does not particularly and distinctly indicate which chemical groups the cycloalkyl may be substituted with, nor does the specification provide such a clear and limiting definition. Therefore this vague limitation renders these claims indefinite, and one of ordinary skill in the art would be unable to ascertain the scope of compounds encompassed thereby. It is suggested that Applicant amend the claims to specify a clear and distinct set of functional groups with which the cycloalkyl structure may be substituted. In particular, it is suggested that the phrase, "R² is substituted or unsubstituted norbornyl," in claim 3 be deleted from the claim, in order to put the claim in condition for allowance, as the structural drawing included in this claim provides a narrower limitation than the aforementioned phrase.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 21, and 23 are rejected under 35 U.S.C. 112, first paragraph,

because the specification, while being enabling for methods of treating ischemic and inflammatory disorders of the central nervous system, and pharmaceutical composition comprising a compound of claim 1 and a specific and particular additional pharmaceutical agent for treating ischemia or inflammation, does not reasonably provide enablement for treating neurodegenerative, neurological, or immunological disorders, or for pharmaceutical compositions directed to treating such disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is directed to a method of treating various neurodegenerative, neurological, ischemic, or inflammatory disorders by administering an active pharmaceutical compound, as well as to pharmaceutical compositions comprising said compound and an additional therapeutic agent.

The state of the prior art: The compounds used in the claimed invention are known in the prior art to be inhibitors of c-JUN N-terminal kinases. Although these kinases are known to be involved in various disorders including neurodegenerative, neurological, ischemic, and inflammatory disorders, these particular compounds have not been evaluated as therapeutic agents. In addition, as the compounds are not demonstrated to be useful for the treatment of any particular disorders, pharmaceutical compositions comprising these compounds and an additional therapeutic agent are not known in the art.

Neurodegenerative and neurological disorders are very broad categories which encompass specific conditions having different causes, biological pathways, and symptoms, and which are not generally treated with the same therapeutic agents. For example, Alzheimer's disease and Parkinson's disease, although both classified as neurodegenerative disorders, are treated with different medications.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The pharmaceutical art is complex, requiring that each embodiment be evaluated on its own merits. The fact that two or more disorders involve the same biological pathway or molecular target does not necessarily indicate that a therapeutic agent useful for treating one disorder will be

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useful for treating all other disorders with any similarity to the treated disorder. This unpredictability can arise from a variety of factors, such as differing activities of the therapeutic agent against different homologues of the same enzyme, differing bioavailability of the agent in different tissues, or other complicating factors. Therefore the activity of a given therapeutic agent against a particular disease is unpredictable in the absence of any *in vitro* or *in vivo* data from a relevant experimental system.

The Breadth of the claims: The instant claims encompass methods of treatment and pharmaceutical compositions directed toward neurodegenerative, neurological, ischemic, and inflammatory disorders. Neurodegenerative disorders include, for example, Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis. Neurological disorders include, in addition to neurodegenerative disorders, all other abnormalities of the brain, including such disorders as neurogenic pain, brain cancer, Creutzfeldt-Jakob Disease, Huntington's disease, epilepsy, and infectious diseases of the central nervous system. Immunological disorders include both autoimmune disorders and immune deficiency disorders. The breadth of the claimed invention includes methods of treating disorders recited in instant claims 21 as well as compositions for treating disorders treatable by the additional therapeutic agents recited in instant claims 20 and 23. The listing of therapeutic agents in these claims is very broad and includes compounds which are otherwise unrelated.

The amount of direction or guidance presented: The claimed compounds are tested in *in vitro* models of ischemia and inflammation, and several of the tested compounds are found to be useful inhibitors of these conditions. It should be noted that

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while the sets of compounds useful in the two models overlap, they are not identical, further indicating that a model of one disorder associated with JNK cannot reliably predict the efficacy or lack thereof of a compound against a different such disorder.

The presence or absence of working examples: No working examples are provided of an actual therapeutic method.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the treatment of neurodegenerative, neurological, ischemic, or inflammatory disorders. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention for the treatment of all neurodegenerative, neurological, ischemic, or inflammatory disorders, one skilled in the art would be required to test the disclosed compounds in appropriate models of various neurodegenerative, neurological, and immunological disorders. In addition, in order to be enabled for a combination of the disclosed compounds with an additional pharmaceutical agent, one skilled in the art must have a clear motivation for combining the two compounds, such as the knowledge that they are both useful for treating the same conditions, thus requiring experimentation to determine which disorders the claimed compounds are useful for treating.

Because these classes of disorders are complex, a significant number of models would be needed. Such experiments would involve both *in vitro* and *in vivo* models. Animal experiments involve, along with the actual experimentation, additional burdens associated with the care and feeding of animals, compliance with ethical and regulatory

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requirements, and disposal of dead animals after the experiment is complete. Performing these experiments for a representative sample of compounds for every distinct disorder encompassed by the categories of neurodegenerative, neurological, and immunological disorders, with no guidance from Applicant's disclosure or reasonable expectation of success, represents an undue experimental burden in order to practice the claimed invention.

Moreover, the specification does not reasonably provide enablement for administering the instant compound in combination with any substances or compounds represented by "an additional therapeutic agent selected from ..." to be those recited in claims 20 and 23, which are seen to be merely functional language and a purely functional distinction.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A

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definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

Note that the specification fails to teach any specific and particular therapeutic agents in co-administering with the instant compound, which can be used in the claimed compositions and particular method of treatments, nor provide working examples, i.e., testing results or data in vitro or vivo to demonstrate the instant compositions (different combinations of the claimed compounds) to be administered to a host, in treating a patient for stroke or inflammation, for example. Hence, in the absence of fully recognizing the identity of the members of the genus "therapeutic agents" herein, one of skill in the art would be unable to fully practice the instant invention without undue experimentation.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the state of the prior art, the breadth of the claims, and the lack of guidance from Applicant's specification, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of disorders other than ischemic and inflammatory disorders, or for pharmaceutical compositions comprising the disclosed compounds and an additional therapeutic agent that is not an anti-inflammatory or anti-ischemic agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (PCT international publication WO01/12621, included with PTO-1449) in view of Silverman. (Reference included with PTO-892) Green et al. discloses a number of isoxazole compounds of a general structure given on p. 14. (lines 18-30, formula IA) The broad limitations of formula IA disclosed in Green et al. include embodiments where the groups R², and G are CH₂(heterocycl) and aryl, respectively, and Q is 2-aminopyrimidine, as disclosed in formula I of instant claim 1. Specific embodiments of the compounds of Green et al. include those in which G is phenyl or 4-fluorophenyl, Q is 2-aminopyrimidine, R² is cyclohexyl or 4-cyclohexanol, and R² is CH₂(piperidinyl). (p. 31, examples XIA-39 – XIA-53) Green et al. also discloses that

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these compounds are useful for the treatment of a number of disorders including inflammatory diseases and reperfusion/ischemia in stroke, heart attacks, and organ hypoxia. (p. 7, lines 15 – p. 8, line 7) Green et al. discloses that a pharmaceutical composition involving these active agents may additionally comprise a pharmaceutically acceptable carrier. (p. 50, lines 1-16) Green et al. further discloses that these compounds may be combined or administered concurrently with additional active agents which are normally administered to treat the condition being treated. (p. 55, lines 9-16) Green et al. does not explicitly disclose the specific compounds of instant claims 1, 2, and 4-18, or the pharmaceutical compositions and methods of instant claims 19-23. Green et al. also does not explicitly disclose a combination of the claimed compounds with therapeutic agents having any of the indications recited by instant claims 20 and 23.

Silverman discloses that the substitution of certain equivalent functional groups, or bioisosteres, in an existing molecule, produces derivatives having similar biological properties. (p. 19, under the heading, "Bioisosterism") In particular, Silverman discloses that rings containing –O-, -S-, -CH₂, or –NH- groups are bioisosteres. (p. 19, table 2.2, no. 5) Therefore compounds containing piperazine, piperidine, and morpholine rings are expected to possess similar biological properties.

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the compounds of formula I disclosed in instant claim 1, and their variants disclosed in instant claims 2 and 4-18. It would also have been obvious to one of ordinary skill in the art to prepare the pharmaceutical compositions of instant claims

19-20 and to use them in the methods of instant claims 21-23. It would also have been obvious to make a pharmaceutical composition comprising a compound of formula I and an additional therapeutic agent as described in instant claims 20 and 23, and to co-administer the compound of formula I and the additional agent as described by instant claim 23.

One of ordinary skill in the art would have been motivated to prepare the compounds of instant claims 1, 2, and 4-18 because these compounds fall within the limitations of the structures disclosed by Green et al., and additionally because the specific functional groups defined in these claims are all disclosed in various embodiments of Green et al., particularly examples XIA-39 – XIA-53. In particular, in view of Silverman's teaching that –O-, -S-, -CH₂, or –NH- groups are bioisosteric when appearing in rings, one of ordinary skill in the art would have been motivated to prepare bioisosteres of the disclosed compounds of Green et al., including the compounds of the claimed invention. One of ordinary skill in the art would have been motivated to prepare the pharmaceutical compositions of instant claims 19-20 and practice the methods of claims 21-23 because Green et al. discloses that the compounds of formula IA are useful for treating inflammatory diseases and ischemia. Additionally, one of ordinary skill in the art would have been motivated to practice these compositions and methods with additional active agents, particularly an anti-inflammatory agent, an anti-asthma agent, or a treatment for stroke, as claimed by instant claims 20 and 23 because these additional components are appropriate therapeutics for the disorder being treated, and because Green et al. discloses that the related compounds of Green

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et al. may be administered along with additional therapeutic agents appropriate to the disorder being treated.

One of ordinary skill in the art would reasonably have expected success in preparing the compounds of instant claims 1, 2, and 4-18 because these compounds fall within the limitations of formula IA of Green et al. and are substantially similar to various embodiments disclosed by Green et al. One of ordinary skill in the art would have reasonably expected success in practicing the therapeutic compositions and methods of instant claims 19-23 because these compositions and methods are directed toward the treatment of diseases which the claimed compounds are already known to be useful for treating. Furthermore, it has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-19, and 21-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6693108 (Reference cited in PTO-892, herein referred to as '108) in view of Silverman. (Reference included with PTO-892) Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds included within the structure of formula I of instant claim 1 fall within the limitations of the species claimed in claims 1-11 of '108. Claims 1-6 of '108 claims a number of isoxazole compounds of a general structure which includes embodiments where the groups R², and G are CH₂(heterocyclyl) and aryl, respectively, and Q is 2-aminopyrimidine, as disclosed in formula I of instant claim 1. Claim 7 of '108 claims specific embodiments of this structure, including those in which G is phenyl or 4-fluorophenyl, Q is 2-aminopyrimidine, R² is cyclohexyl or 4-cyclohexanol, and R² is CH₂(piperidinyl). (Examples XIA-39 – XIA-53) Claim 8 of '108 discloses a pharmaceutical composition comprising any of the compounds of claims 1-7 of '108 and a pharmaceutically acceptable carrier, as claimed in instant claim 19. Claims 9-11 of '108 claim methods of using these compounds to treat various diseases, including

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inflammatory diseases and ischemia. Claims 1-11 of '108 do not explicitly disclose the specific compounds of instant claims 1, 2, and 4-18, or the pharmaceutical compositions and methods of instant claims 19-23.

Silverman discloses that the substitution of certain equivalent functional groups, or bioisosteres, in an existing molecule, produces derivatives having similar biological properties. (p. 19, under the heading, "Bioisosterism") In particular, Silverman discloses that rings containing –O-, -S-, -CH₂, or –NH- groups are bioisosteres. (p. 19, table 2.2, no. 5) Therefore compounds containing piperazine, piperidine, and morpholine rings are expected to possess similar biological properties.

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce the compounds of formula I disclosed in instant claim 1, and their variants disclosed in instant claims 2 and 4-18. It would also have been obvious to one of ordinary skill in the art to prepare the pharmaceutical compositions of instant claims 19-20 and to use them in the methods of instant claims 21-23.

One of ordinary skill in the art would have been motivated to prepare the compounds of instant claims 1, 2, and 4-18 because these compounds fall within the limitations of the structures disclosed by claims 1-6 of '108, and additionally because the specific functional groups defined in these claims are all disclosed in various embodiments of claim 7 of '108, particularly examples XIA-39 – XIA-53. In particular, in view of Silverman's teaching that –O-, -S-, -CH₂, or –NH- groups are bioisosteric when appearing in rings, one of ordinary skill in the art would have been motivated to prepare bioisosteres of the disclosed compounds of claim 7 of '108, including the compounds of

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the claimed invention. One of ordinary skill in the art would have been motivated to prepare the pharmaceutical compositions of instant claim 19 and practice the methods of claims 21-22 because claims 9-11 of '108 are directed toward methods of using these compounds for the treatment of disorders including inflammatory diseases and ischemia.

One of ordinary skill in the art would reasonably have expected success in preparing the compounds of instant claims 1, 2, and 4-18 because these compounds fall within the limitations of formula **IA** of claims 1-6 of '108 and are substantially similar to various embodiments disclosed by claim 7 of '108. One of ordinary skill in the art would have reasonably expected success in practicing the therapeutic compositions and methods of instant claims 19-23 because these compositions and methods are directed toward the treatment of diseases which the claimed compounds are already known to be useful for treating and which are claimed by claims 9-11 of '108.

Summary

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner
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8/14/06

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